



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 175, 176, 177, and 178

[Docket No. FDA-2016-F-1253]

Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; Filing of Food Additive Petition; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notice of filing that appeared in the Federal Register of May 20, 2016 (81 FR 31877). In the notice, we requested comments on a filed food additive petition (FAP 6B4815), submitted by the Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science In The Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council, proposing that we amend and/or revoke specified regulations to no longer provide for the food contact use of specified ortho-phthalates. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the notice of filing of a food additive petition published on May 20, 2016 (81 FR 31877). Submit either electronic or written comments by September 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-F-1253 for "Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; Filing of Food Additive Petition." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing

and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kelly Randolph, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1188.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 20, 2016 (81 FR 31877), FDA published a notice of filing of a food additive petition (FAP 6B4815) submitted by the Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council, c/o Mr. Thomas Neltner, 1875

Connecticut Ave., N.W., Suite 600, Washington, D.C. 20009. The notice invited comments on the petition. The petition proposes that we amend and/or revoke specified regulations to no longer provide for the food contact use of specified ortho-phthalates. Specifically, the petitioners request that we consider that ortho-phthalates are a class of chemically and pharmacologically related substances, and state that there is no longer a reasonable certainty of no harm for the food contact uses of the specified ortho-phthalates. If we determine that new data are available that justify amending the specified food additive regulations in 21 CFR parts 175, 176, 177, and 178 so that they will no longer provide for the use of the ortho-phthalates, we will publish such an amendment of these regulations in the Federal Register, as set forth in § 171.130 and § 171.100 (21 CFR 171.100).

We have received a request for a 60-day extension of the comment period for the petition. The request conveyed concern that the 60-day comment period does not allow sufficient time to collect and provide data and information and develop a meaningful and thoughtful response to the assertions set forth in the petition.

FDA has considered the request; however, because the request was submitted too late to allow us to extend the comment period, we are, instead, reopening the comment period until September 19, 2016. We believe that re-opening the comment period until that date allows adequate time for interested persons to submit comments without significantly delaying our review.

Dated: August 2, 2016.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

[FR Doc. 2016-18720 Filed: 8/5/2016 8:45 am; Publication Date: 8/8/2016]